

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents
July 19, 2007

ACTION REQUEST

Subject: Clinical Study and Research Agreement between the University of Michigan and Ablation Frontiers, Inc.

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the Proposal Approval Form that then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflicts of interest will be developed and approved by the Medical School Conflict of Interest Board and agreed to by the parties involved.

This proposed agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Drs. Hakan Oral and Fred Morady, are both partial owners of Ablation Frontiers, Inc. ("Abalation"), a for-profit company, and are both employees of the University of Michigan ("University"). Dr. Morady also is Chair of the Board of Directors, and Dr. Oral serves as a director. The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents.

Background:

Drs. Oral, Associate Professor of Internal Medicine, and Morady, Professor of Internal Medicine, are partial owners of Ablation. Dr. Morady also is Chair of the Board of Directors, and Dr. Oral serves as a director.

Ablation now wishes to provide an agreement to the University to enable the University to carry out a clinical investigation plan entitled "Tailored Treatment of Permanent Atrial Fibrillation ("TTOP AF Trial").

Nature of the Agreement:

The University proposes to enter into an agreement with Ablation as the sponsor of the TTOP AF Trial. The Principal Investigator for the TTOP AF Trial at the University is Dr. Aman Chugh, Assistant Professor of Internal Medicine, who has no financial or management interest in Abalation.

Agreement Terms:

The terms of the Agreement will conform to University policy. The Agreement calls for total funding of \$64,787 and is anticipated to cover a two year period beginning upon the signing of the Agreement. The University's standard agreement provisions will apply. Since research agreements are often amended, the Agreement includes provisions for amendments to be made but requiring that they be in writing and signed by authorized representatives of both Ablation and the University. University

procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

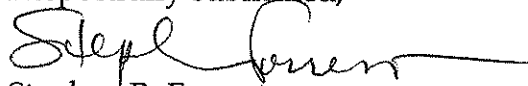
Impact of the Agreement:

The Agreement will permit the participation of the University and will assist the University and Ablation in advancing treatments in the area of Permanent Atrial Fibrillation.

Recommendation:

This matter will be reviewed and approved by the Medical School Conflict of Interest Board. In light of this disclosure and our finding that the Agreement will conform to standard University practices, I recommend that the Board of Regents approve of the University entering into this Agreement with Ablation Frontiers, Inc.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Stephen R. Forrest", with a long horizontal flourish extending to the right.

Stephen R. Forrest
Vice President for Research

July 2007